

REMARKS

This amendment responds to the final Office Action mailed September 2, 2008. Claims 60-67 and 69 were pending in the Application prior to this amendment and stand rejected only under 35 U.S.C. §112. Claim 69 has been canceled.

Applicants thank the Examiner, William H. Matthews, for the courtesies extended to Applicants' representative, David W. Dorton, during the telephone interview conducted October 20, 2008. Claim 60 was discussed with respect to the interpretation of the term "coupled," as discussed more fully below. Applicants respectfully request reconsideration in view of the following remarks.

Claims Rejected under 35 U.S.C. §112

Claims 60-67 and 69 stand rejected under 35 U.S.C. §112, first paragraph, with respect to the recitation of "three or more non-plicating fasteners configured to be individually fixed to tissue adjacent the annulus of the heart valve," and "an elongate tensioning element coupled with the non-plicating fasteners," as recited in claim 60, and also with respect to the recitation of "elongate members having first and second terminal ends and being coupled to the tensioning element at a location intermediate the terminal ends," as recited in claim 69. Claim 69 has been canceled without prejudice, and reserving the right to pursue the subject matter of this claim in a continuing application. Accordingly, the rejection of claim 69 is moot.

Applicants respectfully traverse the rejection of claim 60 under 35 U.S.C. §112, first paragraph because the Application describes the invention in sufficient detail that

persons skilled in the art would understand that the Applicants had possession of the claimed invention, and would understand how to make and use the claimed invention, based on the application disclosure.

"The written description requirement of 35 U.S.C. §112, first paragraph, is separate from the enablement requirement found in the same provision of 35 U.S.C. §112. . . . Satisfaction of the 'written description' requirement does not require *in haec verba* antecedence in the originally filed application." Staehelin v. Secher, 24 USPQ2d 1513, 1519 (BPAI 1992). "Adequate description under the first paragraph of 35 U.S.C. §112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." Ex parte Parks, 30 USPQ2d, 1234, 1236-37 (BPAI 1993). "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." See, e.g., Moba, B.V. v. Diamond Automation, Inc., 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d at 1116 (Fed. Cir. 1991); MPEP §2163(I). "The Examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims." MPEP §2163(II)(A)(3)(b).

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information know in

the art without undue experimentation." In re Buchner, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); MPEP §2164.01. The Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. See, In re Wright, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); MPEP §2164.04.

The Application at page 15, line 23, through page 16, line 4, describes how fasteners (e.g., T-Bars 1112) are coupled with the tensioning element 1140 by way of the implant 1124. Specifically, the T-Bars 1112 secure the implant 1124 to the tissue, and the tensioning element 1140 is inserted within the implant 1124. The implant may thereafter be shortened by applying tension to tension element 1140 to thereby reduce or eliminate a gap between the leaflets of a mitral valve, as described in the Application at page 16, lines 6-13. Accordingly, Applicants assert that persons of ordinary skill in the art would understand that Applicants had possession of the invention set forth in claim 60 based on the disclosure, including page 15, line 23, through page 16, line 4, and FIGS. 11A, 11B. Moreover, persons of ordinary skill in the art would certainly be able to make and use the invention set forth in claim 60 based on the disclosure, including the passages noted above.

In rejecting the claims under 35 U.S.C. §112, first paragraph, the Examiner has failed to explain how or why persons skilled in the art would not recognize a description of the claimed invention, or how or why persons skilled in the art would not understand how to make and use the claimed invention. For at least the reasons discussed above, Applicants respectfully request that the rejections of claim 60 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 61-67 each depend from independent claim 60 and are therefore in condition for allowance for at least the reasons discussed above with respect to claim 60. Accordingly, Applicants respectfully request that the rejections of claims 61-67 under 35 U.S.C. §112, first paragraph, also be withdrawn.

Conclusion

In view of the foregoing remarks and amendments to the claims, Applicants believe this application is in condition for allowance and respectfully request allowance of the pending claims. If the Examiner believes any issue requires further discussion, the Examiner is respectfully asked to telephone the undersigned attorney so that the matter may be promptly resolved. The Examiner's prompt attention to this matter is appreciated.

Applicants do not believe that any fee is due in connection with this submission. However, if any fees are necessary to complete this communication, the Commissioner may consider this to be a request for such and charge any necessary fees to Deposit Account No. 23-3000.

Respectfully submitted,

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